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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,443	06/22/2000	John Ernest Sims	03260.0044	5571

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/598,443	SIMS, JOHN ERNEST	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/21/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

1b. Applicants' arguments and information disclosure statement filed on 21 July 2004 have been considered. Claims 1-33 have been cancelled. Claims 34-60 pending and under consideration.

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2a. Claims 34-60 stand rejected under 35 U.S.C. 101, for reasons of record, set forth in the office actions mailed on 11/26/02 in Paper No:11, pages 3-7, and 21 August 2003, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims 34-60 are directed to an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO: 1 , and encoding the polypeptide of SEQ ID NO:2 . The nucleic acid of SEQ ID NO: I is described as being an isolated SIGIRR (single Ig IL-R related molecule), encoding the SIGIRR polypeptide of SEQ ID NO:2. The instant specification discloses that SIGIRR polypeptide is homologous to members of the IL-1 receptor family, sharing 26%

identity to IL-IR type 1, 32% amino acid identity to IL-IR AcP, 35% amino acid identity with 1L-a J4.1-171 and 33% homologous with TIGIRR, (see page 9, lines 5-10). The specification also states that although SIGIRR is homologous to IL-IR family, the N-terminal domain is predicted to function poorly as a signal peptide, (see page 9, lines 19-22). One asserted utility for claimed nucleic acid, is to be used to express the encoded protein. However, beyond disclosing that the human protein encoded by the claimed nucleic acid shares structural homology to known IL- I receptor family, the specification does not disclose the biological and functional properties of this protein. The specification provides exemplary binding assays (pages 34-36), however, there is no evidence that the SIGIRR protein encoded by the claimed nucleic acid has been tested in these assays, and if so, whether a binding partner has ever been identified for this protein. Furthermore, the members of the IL-1 family have diverse biological activities, therefore, being a member in this family, does not impart activities common to all of the members.

The claimed invention is directed to a nucleic acid encoding a receptor that no function or biological significance was determined for, at the time the instant application was filed. There is little doubt that, after further characterization, and once the specific ligand, function and role of the SIGIRR of the instant invention is ascertained, it would have a specific, substantial and credible utility, however, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. Therefore, there is no specific and

substantial or well-established utility for the claimed nucleic acid. The fact that the protein encoded by the claimed nucleic acid might be a member of the IL-l receptor family is not enough to establish a specific and substantial utility or a well established utility for it.

2b. Claims 34-60 are also rejected under 35 U.S.C. 1 12, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification only discloses a deduced amino acid sequence for the protein encoded by the claimed nucleic acid. It does not disclose an activity for it, does not disclose a ligand for it, and does not disclose the physiological role of the protein encoded by the claimed nucleic acid, therefore the skilled artisan would not know how to use the nucleic acid having nucleotide sequence set fol'th in SEQ ID No: I or the protein encoded by said nucleic acid.

Should Applicants establish an activity for the polypeptide of SEQ ID NO:2 encoded by the polynucleotide of SEQ ID NO: 1, instant specification would still fail to adequately describe and enable an isolated nucleic acid that hybridizes to the nucleic acid of SEQ ID NO:1 and encodes an amino aeid sequence that is at least 80% or 90% identical to amino acid 1- 118 of SEQ ID NO:2, or a nucleic acid comprising a DNA that is at least 80% or 90% to the polynucleotide of SEQ ID NO:1, Applicants do not provide any guidance as to which of the myriad of polypeptide species that share 80% or 90% to the polypeptide of SEQ ID NO:2,

from amino acid residue 1 to 118, which are encoded by a polynucleotide that hybridizes to the claimed nucleic acid, will retain the characteristics of the polypeptide of SEQ ID NO:2, therefore, the claims broadly encompass a significant number inoperative species. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polynucleotide having at least 80% or 90% sequence identity to SEQ ID NO:1, which encodes the polypeptide of SEQ ID NO:2, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention an isolated nucleic acid that hybridizes to the nucleic acid of SEQ ID NO:1 and encodes an amino acid sequence that is at.least 80% or 90% identical to amino acid 1-118 of SEQ ID NO:2, or a nucleic acid comprising a DNA that is at least 80% or 90 % to the polynucleotide of SEQ ID NO: 1, would be undue. For example, Applicants do not teach which regions of the polypeptide of SEQ ID NO:2 can tolerate mutations, without affecting the activity of said polypeptide. Thus without information regarding which regions of the polypeptide of SEQ ID NO:2 are critical to a specific function, the full scope of the claimed invention is not enabled. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial

inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occuning nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

Response to Applicants' arguments:

Applicant present the following arguments regarding the rejection of claims 34-60 under 35 U.S.C. § 101/112.

Applicants cite Example 10 of the USPTO Revised Interim Utility Guidelines, and argue that the fact pattern in the instant application is directly analogous to the fact pattern in Example 10. Applicants argue that SEQ ID NO:1 of the instant invention is identified as having sequence homology with IL-1R and that the IL-1R proteins were known in the art at the time the application was filed. applicants submit that the Examiner has not provided any evidence why the claimed invention lacks credible, specific and substantial utility. Applicants also submit numerous post filing references that allegedly corroborate that the utility of SIGIRR as IL-1R receptor is credible, substantial and specific utility. Applicants contend that Wald et al expressly confirms that SIGIRR is an IL-1 receptor family member that negatively regulates immune responses. O'Neil et al also disclose that SIGGIR puts brakes on Toll-like receptors, while Mantovani et

al teach that TIR8/SIGIRR is decoy in the tuning of inflammatory cytokines and toll-like receptors. Thus, Applicants conclude that these references corporate that the claimed invention is an IL-1R.

These arguments are not deemed persuasive. With respect to Applicants' first argument, although Applicants asserted that the protein of the instant invention might be a member of IL-1R family, the biological role of this protein was never disclosed. The fact pattern of the instant invention differs from that of Example 10 of the USPTO Revised Interim Utility Guidelines, because the members of the IL-1 family have diverse biological activities, therefore, being a member of this family, does not impart activities common to all of the members. Whereas a broad class of enzyme such as the ligases have a general utility in such an application as ligation of DNA for cloning purposes which is essentially applicable to all of the members of that class. Since the specific biological role of the claimed invention has not been disclosed, the claimed invention does not have a well established. According to the USPTO Revised Interim Utility Guidelines. A well established utility is a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. In the instant case, one of ordinary skill in the art would not have known how to use the protein of instant invention, simply, because it might be a member of the IL-1R family.

The post filing date references cited by Applicants cannot be relied upon to establish a specific and substantial utility, because the instant specification

never asserted that the protein of the instant invention regulates the immune system negatively. The specification states that although SIGIRR is homologous to IL-IR family, the N-terminal domain is predicted to function poorly as a signal peptide, (see page 9, lines 19-22). The specification also discloses that the extracellular portion of SIGIRR polypeptide is unlikely to bind to IL-I family ligand, since it has a single Ig domain rather than the typical three Ig domains. Thus the specification did not disclose a function or role for the protein of the instant invention. However, all of the post-filing date references cited by the Applicants, disclose that the SIGGIR protein is a negative regulator of the IL-1 and TLR signaling, although, this was never asserted by the Applicants. One of ordinary skill in the art would not have known how to use the protein of the instant invention at the time the instant application was filed. The protein of the instant invention needed further characterization, to determine its function and its biological significance, so that it would have a specific, substantial and credible utility, however, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility.

Claim Rejections - 35 U.S.C. §112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 59-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claim 59 recites the acronym "TIGIRRI", which renders the claim unclear, because it is unclear what the acronym stands for, and more than one protein can be known for the same acronym.

In the response filed on 27 May 2003, Applicant argued that the acronym TIGIRR is in fact the proper name for the subject nucleic acids and polypeptides, and that Applicant is entitled to name any novel sequence he sees fit, and that includes using a name that arose from an acronym. Since there is no other sequence known to Applicant's representative with the same name as TIGIRR, and since the name TIGIRR has been accepted by the scientific community as properly denoting the sequences shown in SEQ ID Nos:l and 2.

Although Applicant is entitled to be his own lexicographic, however, it is confusing whether the protein of the instant invention is known as "SIGIRR" or "TIGIRR". The instant specification refers the polypeptide of the instant invention as "SIGIRR" and the post filing references filed by Applicant also identify this protein as "SIGIRR". Clarification is required.

Conclusion :

4. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is

(571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
20August 2004

JANET ANDRES
PRIMARY EXAMINER